

MEDIA ADVISORY STANDARDS WORKING GROUP TO FINALIZE DRAFT REGULATIONS FOR RESEARCH FUNDED BY THE CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE

Posted: January 26, 2006

SAN FRANCISCO, CA – Next Monday and Tuesday (January 30 – 31), the Scientific and Medical Accountability Standards Working Group ("Standards Working Group"), chaired by Sherry Lansing and Bernard Lo, M.D., will meet in Los Angeles to finalize their recommendations for the Independent Citizens' Oversight Committee (ICOC) on the medical, ethical, and scientific standards governing stem cell research funded by the California Institute for Regenerative Medicine (CIRM).

WHO: Standards Working Group, a nineteen member group comprised of patient advocates (5) and the Chairman of the ICOC, and nationally recognized scientists (9) and ethicists (4).

WHAT: After five public meetings and three public sessions to solicit public comments, the Standards Working Group is expected to finalize the Draft CIRM Regulations and submit them to the ICOC to consider on Friday, February 10 at Stanford.

Under the proposed regulations, CIRM will be the first agency to:

- legally mandate specialized review by a Stem Cell Research Oversight (SCRO) committee;
- enhance state and federal policies in the areas of voluntary-informed consent;
- and ensure that women's reproductive needs are protected and prioritized before the research.

This draft reaffirms the requirements of Proposition 71, namely a ban on human reproductive cloning and a prohibition of payment to egg donors in the state of California.

Once ratified by the ICOC, the regulations will enter into the formal rule-making process governed by the Administrative Procedures Act and have the force of California law. During this time, the CIRM will solicit further public comment and input on the medical and ethical regulations.

WHEN: MONDAY, JANUARY 30/9:00 AM – 5:00 PM (Estimated)
TUESDAY, JANUARY 31/8:30 AM – 1:00 PM (Estimated)

WHERE: Luxe Hotel Sunset Boulevard
Room: Luxe Sunset Ballroom 1
11461 Sunset Boulevard
Los Angeles, CA 90049

WHY: The Standards Working Group makes recommendations to the 29-member ICOC that governs the CIRM on scientific, medical and ethical standards pertaining to stem cell research the institute funds. The Standards Working Group, appointed on May 6, 2005, also makes recommendations to the ICOC on compliance of adopted standards, as well as on modifications to standards.

Background: The CIRM draft regulations are based on the Guidelines for Human Embryonic Stem Cell Research, the landmark document published by the National Academies of Science (NAS) in May 2005. Two members of the Standards Working Group served on the NAS blue ribbon committee to develop the Guidelines: legal scholar and ethicist Alta Charo (University of Wisconsin) and renowned scientist Janet Rowley (University of Chicago).

In addition to holding five meetings around the state since last July, the Standards Working Group has heard public comment at public workshops in Los Angeles, Sacramento, and San Francisco that were designed to go beyond what is required by law to capture public input. To date, the group has received and addressed over thirty public comments.

The ICOC approved a draft of these recommended regulations as the interim standards for CIRM-funded research at the November 2nd meeting in San Francisco. The interim standards then returned to the Standards Working Group for further refining before a second ICOC review and then undergoing the APA regulatory-making process.

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